

Pandemic A(H1N1) 2009 Vaccine Production: Preliminary 2010 Survey Results

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Organization



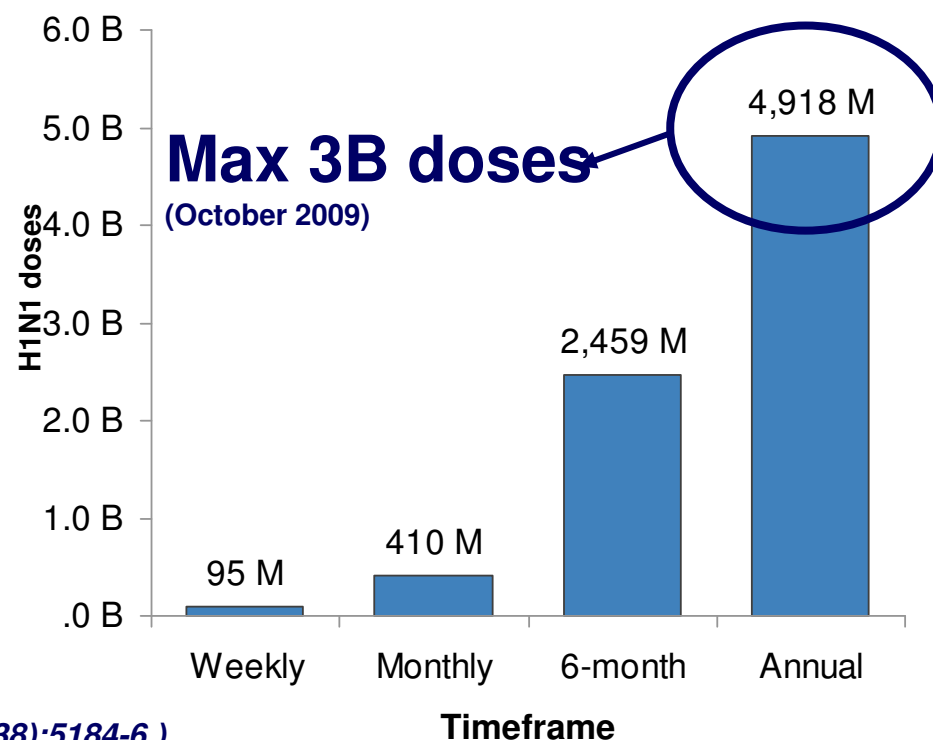
Global pandemic (H1N1) 2009 vaccine production capacity: June 2009 estimate

Assumptions / Methodology

- Survey sent to 36 potential influenza vaccine manufacturers
 - 100% response rate
 - All 21 current influenza vaccine producers responded
 - 26 manufacturers that intend to produce pandemic vaccines
 - Includes LAIV and one recombinant vaccine capacity
- Survey assumes
 - 1:1 H1N1 to seasonal yields
 - Most dose sparing formulation for **each** manufacturer
 - Use of full production capacity

Estimated H1N1 Vaccine Capacity

At 1:1 yields, most dose-sparing formulation, full capacity



Source: WHO survey (Collin N. et al, Vaccine 2009. 27(38):5184-6)

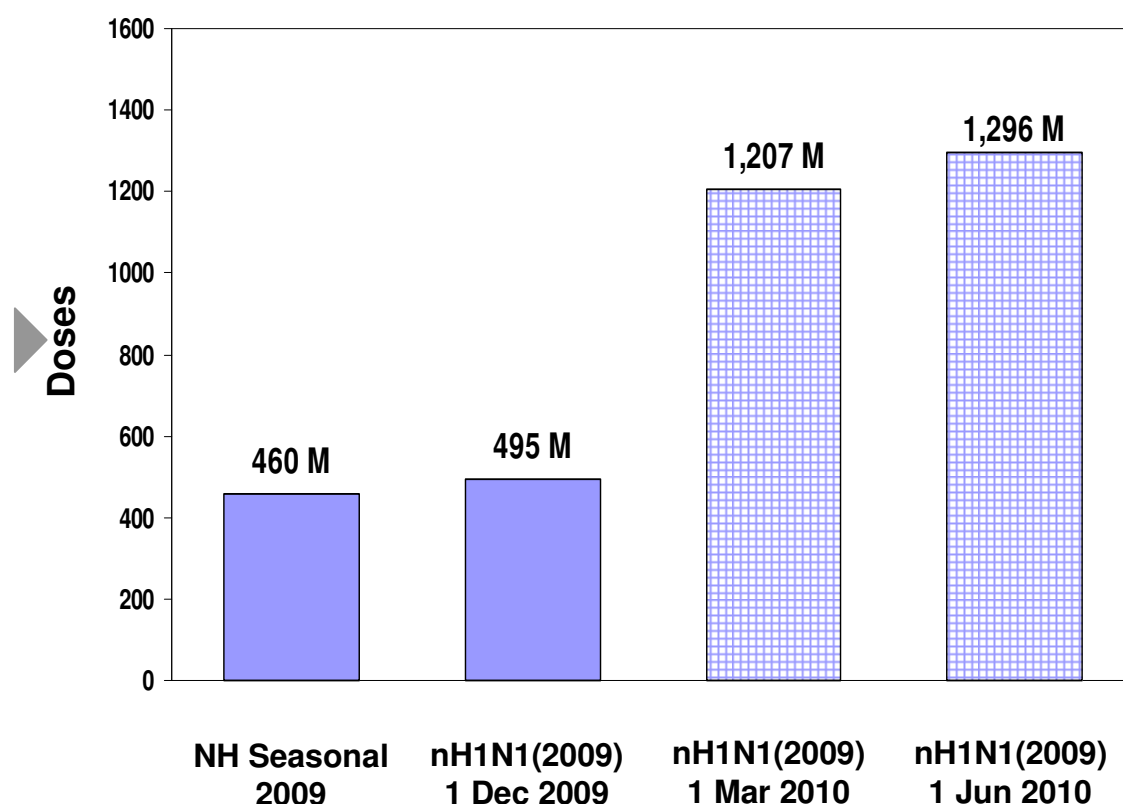
Global pandemic (H1N1) 2009 vaccine production capacity: January 2010*

Methodology

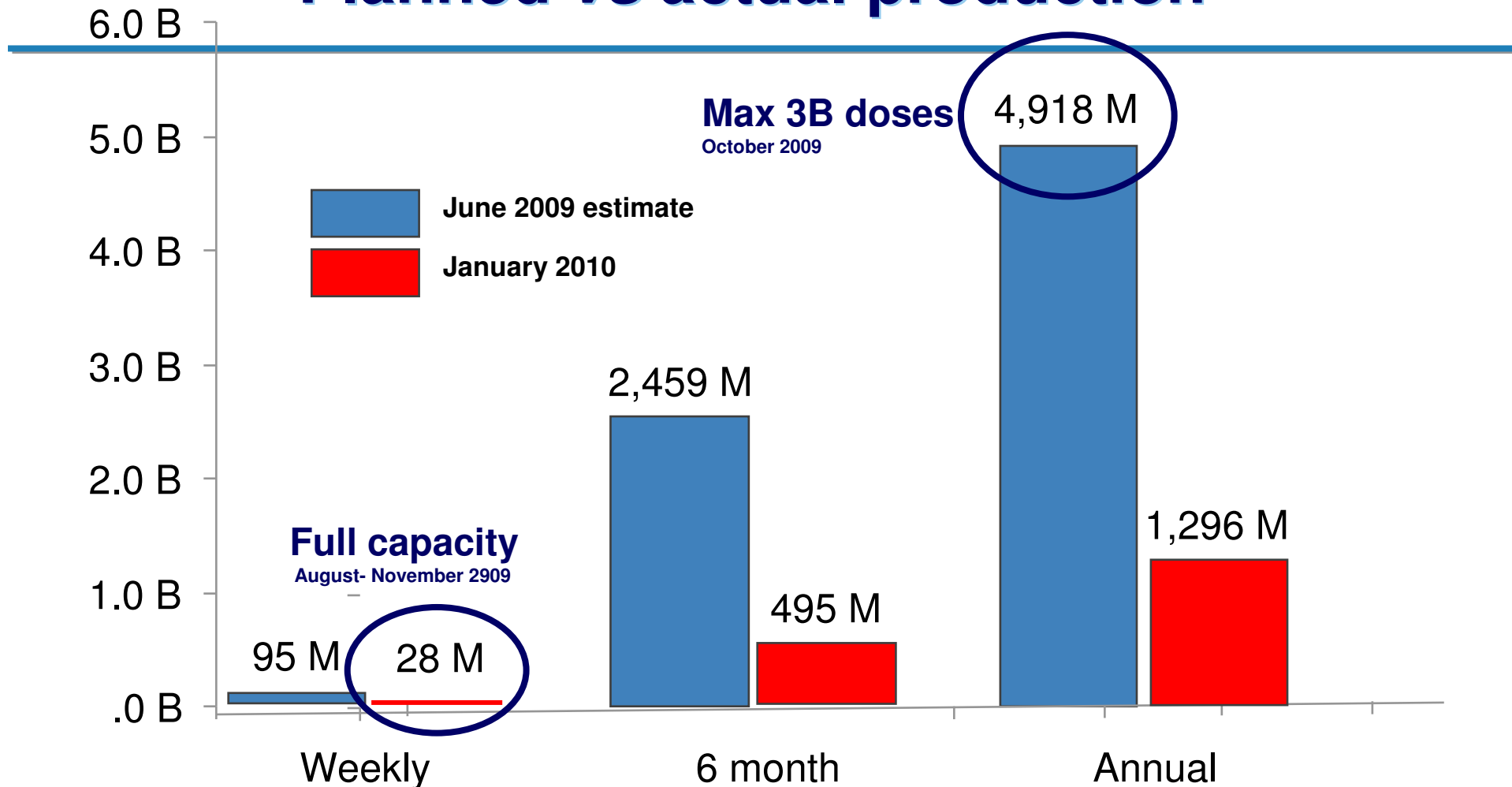
- Survey sent to 30 known or potential influenza vaccine manufacturers
 - Excel® worksheet with Visual Basic Userform technology
 - Analysed using Stata statistical software
 - Investigated each manufacturer's NH and SH seasonal vaccine and nH1N1(2009) pandemic vaccine production
 - Includes LAIV and recombinant vaccine capacity
 - 93% (28/30) response rate

**As of 10 January 2010*

Actual and Estimated Influenza Vaccine Production



Global pandemic (H1N1) 2009 vaccine : Planned vs actual production*



*As of 10 January 2010

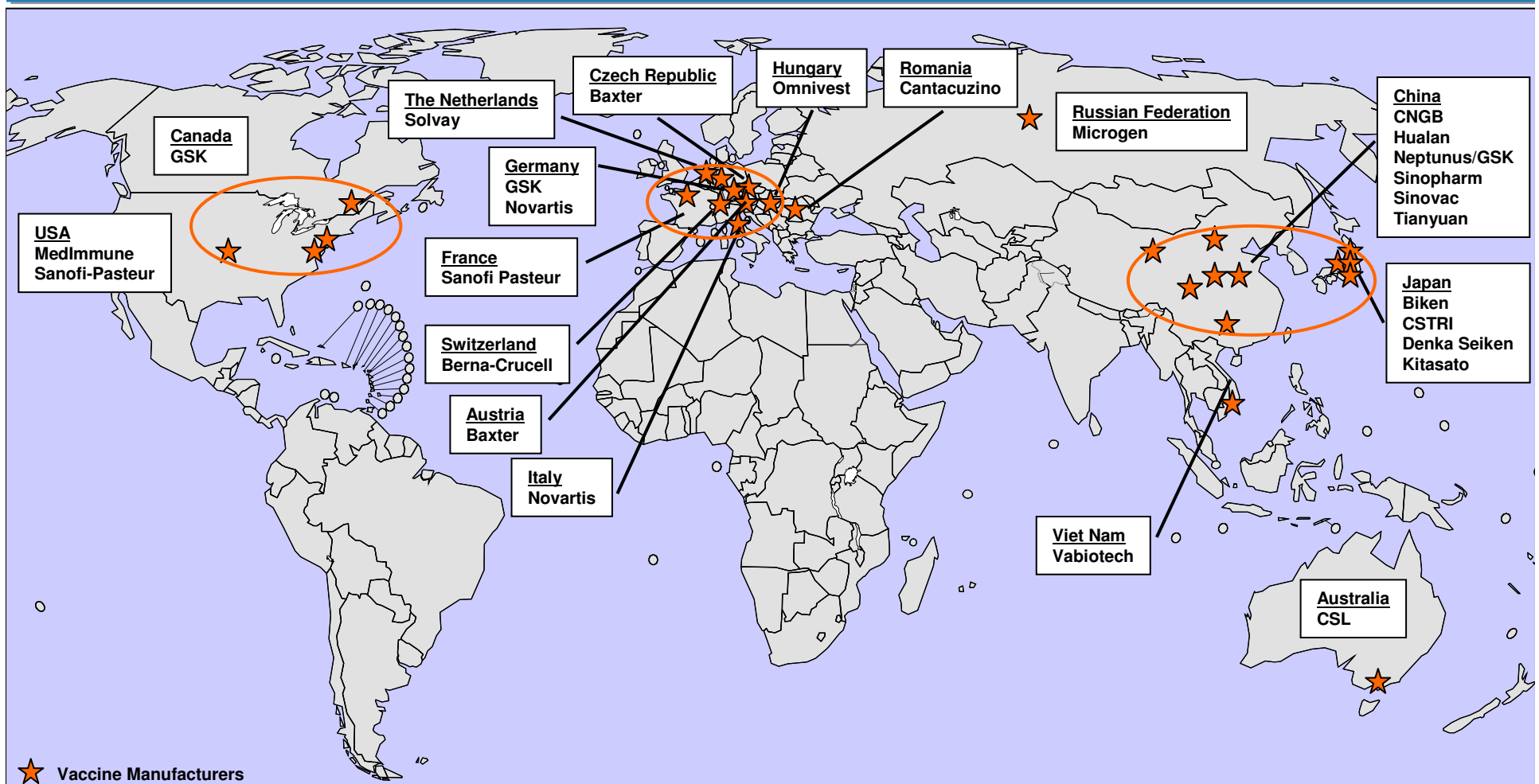
Global seasonal trivalent and pandemic vaccine production capacity – June 2009 vs January 2010

	Total annual capacity (million doses)	2009 planned Northern hemisphere production (million doses)	2009 actual Northern hemisphere production (million doses)	A(H1N1) 2009 vaccine planned production (12 months)	A(H1N1) 2009 vaccine actual production (12 months)	Actual vs planned A(H1N1) vaccine production
Companies A	560	323	350	4,227	983	23%
Companies B	316	170	119	687	313	46%
All	876	493	469	4,914	1,296	26%

Companies A (n=7): those who announced in June 2009 a capacity to produce at least 2.10⁶ doses of new H1N1 vaccine / week

Companies B : other smaller companies

Influenza Vaccine Manufacturers (2007)



New manufacturers since 2007, part of WHO Technology Transfer programme

2007

- **Bio Farma, Indonesia**
- **Birmex, Mexico**
- **Instituto Butantan, Brazil***
- **IVAC, Viet Nam**
- **Governmental Pharmaceutical Organization (GPO), Thailand***
- **Serum Institute of India (SII), India***

2009

- **Cantacuzino Institute, Romania***
- **Green Cross Corporation, Korea***
- **Razi Institute, Iran**
- **Torlak, Serbia**
- **Vacsera, Egypt**

** A(H1N1) vaccine clinical trials in 2009-2010*



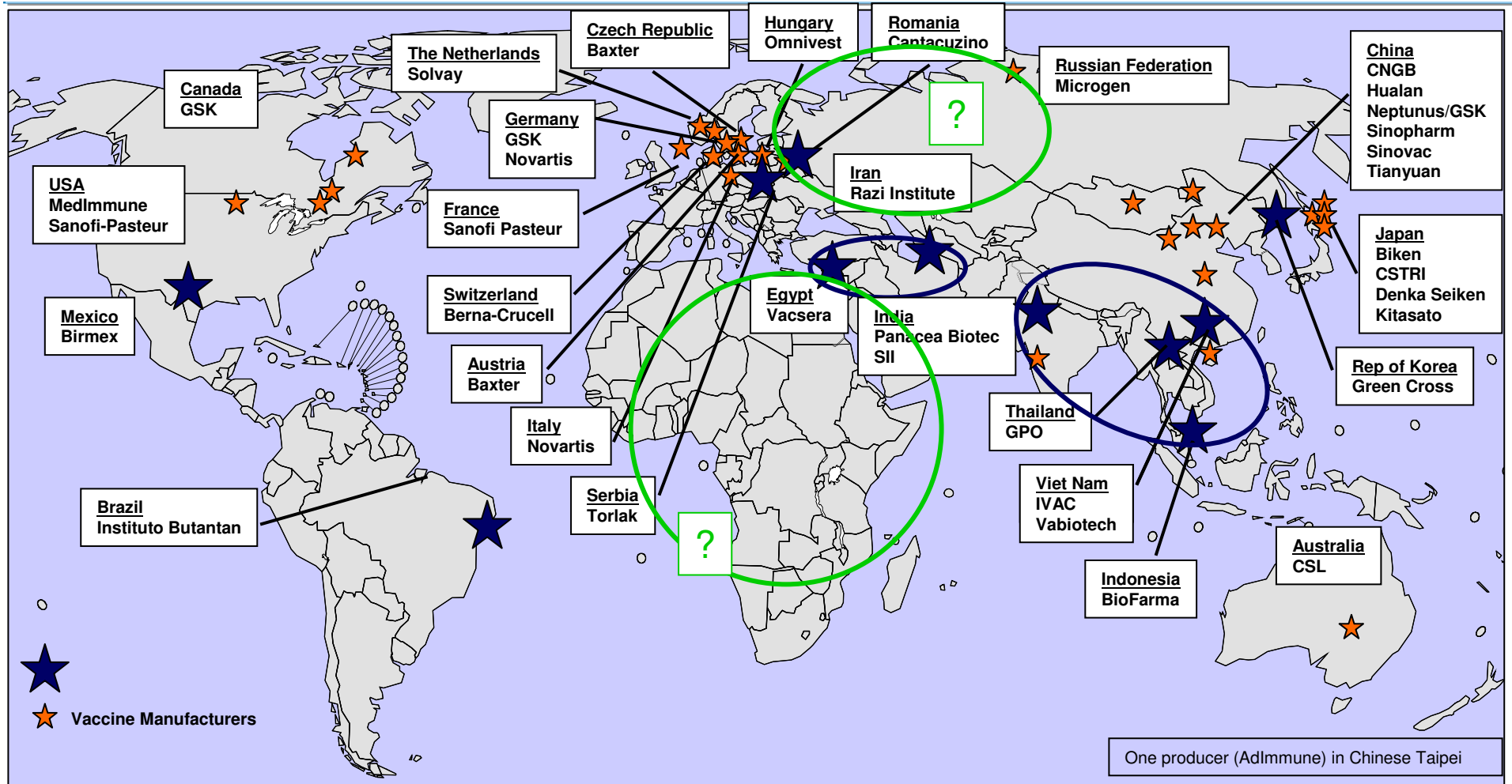
Access to New Technology

WHO provided three developing country vaccine manufacturers with a license on the Russian Live Attenuated Influenza Vaccines (LAIV) technology:

- **Serum Institute of India (SII)**
- **Government Pharmaceutical Organization of Thailand (GPO Thailand)**
- **Zhejiang Tianyuan Bio-pharmaceutical Company in China**

→ GPO Thailand and SII in clinical trials of influenza A(H1N1) 2009 LAIVs.

Influenza Vaccine Manufacturers (January 2010; Actual and Potential)



Conclusions

- Global influenza vaccine production capacity has increased sharply to over 800 million doses trivalent seasonal vaccine from 350 million in 2006;
- Number of pandemic A(H1N1) vaccine produced over a 12 month period is likely to only reach 26% of what was expected in June 2009, which would allow to immunize less than 1.3 billion people globally with a 1-dose regimen;
- New manufacturers have been established in developing countries, which brings hopes to more adequate production capacity and equitable access in case of a future pandemic;
- Adequate production capacity is still lacking in some regions of the world, in particular in sub-Saharan Africa and Eastern Europe.

